

K091593

## Section 5 – 510(k) Summary

**Submitter:** MEDRAD Interventional / Possis  
9055 Evergreen Boulevard NW  
Minneapolis, MN 55433-8003 USA

**Contact Person:** Doug Atkins  
Sr. Regulatory Affairs Associate  
Phone: (763) 450-8060  
Fax: (763) 780-2227  
Email: doug.atkins@possis.com

**Date Prepared:** May 29, 2009

**Trade Name:** AngioJet® Ultra DVX® Thrombectomy Set  
AngioJet® Ultra Xpeedior® Thrombectomy Set

**Classification:** 870.5150 and 870.1210

**Product Code:** DXE and KRA

**Predicate Device(s):** The subject devices are equivalent to the following devices:  
• K071342 and K090253 AngioJet Ultra Xpeedior Thrombectomy Set  
• K072269 and K090253 AngioJet Ultra DVX Thrombectomy Set

**Device Description:** AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are sterile, single use, disposable sets that include a Thrombectomy Catheter and Pump in one combined unit. The AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are used with the AngioJet Ultra Console.

**Intended Use:** The AngioJet Ultra DVX and Xpeedior Thrombectomy Sets are intended for use with the Angiojet Ultra Console to break apart and remove thrombus from :  
\* upper and lower extremity peripheral arteries ≥ 3.0mm in diameter,  
\* upper extremity peripheral veins ≥ 3.0mm in diameter,  
\* iliofemoral and lower extremity veins ≥ 3.0mm in diameter,  
\* A-V access conduits ≥ 3.0mm in diameter and  
\* for use with the Angiojet Ultra Power Pulse Kit for the control and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

**Functional and Safety Testing:** Representative samples of the device underwent mechanical bench testing to demonstrate safety and effectiveness and appropriate functional and performance characteristics.

**Conclusion:** MEDRAD Interventional / Possis considers the AngioJet Ultra DVX and Xpeedior Thrombectomy Sets to be substantially equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.